UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,304	09/05/2003	Andrea M. McPhillips	02972938	8208

26565 7590 01/29/2007

MAYER, BROWN, ROWE & MAW LLP
P.O. BOX 2828
CHICAGO, IL 60690-2828

EXAMINER	
CLAYTOR, DEIRDRE RENEE	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/656,304	MCPHILLIPS ET AL.	
	Examiner	Art Unit	
	Renee Claytor	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 April 2004 and 15 December 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's response and amendments to the claims filed on 12/15/2006 are hereby acknowledged. Applicant's amendments filed on 12/15/2006 are sufficient to overcome the 35 U.S.C. 112- 2nd paragraph rejection in the previous Office Action. Applicant's filing of a terminal disclaimer over U.S. Patent 6,747,058 is sufficient to overcome the obviousness-type double patenting rejection.

Applicant's address the Objection to the Drawings by replacing Figures 20-23. However, in the Office Action mailed on 6/15/2006 it is noted that multiple discrepancies are noted between the description of the drawings in the specification and the label of the drawings disclosed. For example, the specification states that Figure 4 shows dose proportionality assessment following deep-lung inhalation dosing for plasma dronabinol of the First Dose (Day 1) illustrating Cmax/Dose vs. Dose. However, Figure 4 as given illustrates AUC(0-t)/Dose vs. Dose on the axes. Therefore, the Objection to the Drawings is maintained.

Applicant's address the Objection to the Specification by correcting "ηM" typographical errors in the specification. However, not all of the errors were corrected. For example, page 10, line 14 reads "...using aerosol particle diameters of less than about 3 ηM....". Therefore, the Objection to the Specification is maintained.

Applicant's argue that the amendment to Claim 1 is sufficient to overcome the 35 U.S.C. 103(a) rejection because Touitou, Peart, and Vachon do not teach the composition of Claim 1 wherein a single dose of the composition achieves a T_{max} at

least within 0.041 hour. This argument is not found to be persuasive and is considered new matter (explained below).

In view of Applicant's response and amendments to the claims, the following modified objections and rejections are being made.

Claim Objections

Drawings

Multiple discrepancies are noted between the description of the drawings in the specification and the label of the drawings disclosed. Appropriate correction is required.

Specification

The recitation 10 ηM is objected to as a typographical error. This does not correlate with the recitation of 10 μM in the parent application (09/639289).

Claim Rejections – 35 U.S.C. 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the instant case, claim 1 was amended to include the recitation "...a Tmax is achieved at least within 0.041 hour". The recitation of claim 1 is stated broadly and can include any amount of time up to 0.041 hour. However, Table 4 of the Specification teaches the T_{max} of several nebulized doses of dronabinol ranging from 0.032-0.041. Therefore, the Specification only describes a particular range of time and does not describe any amount of time leading up to 0.041 hours.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573).

Touitou teaches a medical composition comprising ethanol (49%), water (29.4%), and propylene glycol (19.6%) in combination with tetrahydrocannabinol (THC; 7 μci/ml) as the active agent (see Table I), which encompasses claims 1-8.

Touitou fails to teach the dosage form of THC and an aerosol form of the composition.

Peart et al. teach a stable aerosol-dispensable pharmaceutical composition comprising a pharmaceutically effective concentration of delta-9-THC (Column 1, lines 20-27; claims), which is absorbed within seconds and delivered to the brain efficiently. Peart et al. also teach that an organic solvent such as ethanol can assist in solubilizing the delta-9-THC (Column 5, lines 50-52; claims). It is further taught that the optimal size of the respirable dose, or the mass of delta-9-THC in particles with aerodynamic diameters small enough to be delivered to and absorbed by the lungs, is less than 10 μm in size (Column 6, lines 37-48), allowing for effective inhalation. A metered dose inhaler (MDI) is also taught for the aerosol administration of delta-9-THC.

Vachon et al. teach propylene glycol and water (in a ratio of 9:1) as a vehicle for holding THC (4.5 g/100ml) to be administered as an inhaled aerosol with a nebulizer (Materials, Methods and Subjects).

Furthermore, it is obvious to vary and/or optimize the mean mass median aerodynamic diameter provided in the composition, according to the guidance provided by Peart et al., to provide a composition having the desired properties such as the desired T_{max}. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou and Peart and form a stable

aerosolable composition with a pharmaceutically effective amount of delta-9-THC because Touitou teaches a composition comprised of ethanol, water, and propylene glycol with delta-9-THC as the active ingredient and Peart teaches an aerosolable composition with a pharmaceutically effective amount of THC. Further it would have been obvious to one skilled in the art at the time the invention was made to further combine the teachings of Vachon who teaches that a vehicle of propylene glycol and water in a ratio of 9:1 is capable of holding up to 4.5 g of THC/100 ml in clear solution, with Touitou and Peart, because both teach THC as a therapeutic agent and a solvent comprising ethanol.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ the composition of Touitou in an aerosolable form of Peart et al. and Vachon et al., for more rapid onset of pharmacological action in the brain after administration of delta-9 THC. One having ordinary skill in the art at the time the invention was made would have been further motivated to employ the composition of Touitou in an aerosolable form of Peart et al. with delta-9 THC particles with aerodynamic diameters less than 10 μm in size to allow for more effective inhalation and absorption by the lungs.

Claims 9-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Touitou (U.S. Patent # 5,716,638) in view of Peart et al. (U.S. Patent # 6,509,005) and Vachon et al. (XP-000965573) as applied to claims 1-8 above and further in view of LaMastro (U.S. Patent # 5,258,336).

Touitou, Peart et al., and Vachon et al. references are discussed above. Peart teaches administration of a composition via a metered dose inhaler (MDI) and Vachon teaches administration via a nebulizer.

Touitou, Peart et al., and Vachon et al. do not teach a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC with Type I Amber Glass.

LaMastro et al. teach a Type I amber glass composition that provides a high degree of chemical stability and protection from ultraviolet light for certain pharmaceutical compositions (Column 1, lines 10-13).

Accordingly, it would have been obvious to one skilled in the art at the time the invention was made to combine the teachings of Touitou, Peart, and Vachon in further view of LaMastro to house the composition in a sterile and/or preserved sealed unit-or multi-unit dosage form of delta-9 THC in Type I amber glass. One having ordinary skill in the art at the time the invention was made would have been motivated to use Type I amber glass because it provides chemical stability and protection from ultraviolet light for pharmaceutical compositions.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is 571-272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER